II. REMARKS

A. In the Claims

Claims 17-21, 23, and 25-28 are pending. Claims 1-16, 22, and 24 were canceled previously. Claims 26-28 are added herein.

Claim 17 has been amended to state that the outer layer components used in the method comprises "polymethacrylate or ethylcellulose." (language added to claim 17 underlined). Basis for this amended language can be found on page 9, lines 1-4 of the specification and in claims 5 and 6, as filed.

New claims 26, 27, and 28 are based on claims 1, 9, and 10 of the present application, respectively, after amendment by Applicants in Paper No. 4 on October 25, 2002. Claim 26 is the same as claim 1, except that the term "glassy matrix" has been omitted and a statement has been added to the claim that the diffusion-limiting sleeve comprising a plasticizer and polymethacrylate or ethylcellulose. (Underlined language added to claim 26). The language of each of new claims 27 and 28 is the same as claims 9 and 10, respectively, except that each claim now depends from claim 26 (claims 9 and 10 depended from claim 1).

Claims 1, 9, and 10, on which claims 26 and 27 are based, were canceled by the Applicants without prejudice in Paper No. 7 on June 19, 2003. Those particular claims were canceled from the present application in order to focus on claims which Applicants believed would be allowed in the next Office Action, based on a statement in the preceding Office Action (Paper No. 6, mailed March 19, 2003) that all the then pending method claims were free of the prior art and "would be in a condition of allowance upon clarification of 35 USC 112 (indefiniteness) rejections of claim 17."

Applicants respectfully submit that none of the amendments to the claims introduced herein, including the new claims added herein, introduce any new matter to the application. Applicants submit, furthermore, that new claims 26 and 27 are patentable for the same reasons given herein below for claims 17-21, 23, and 25.

B. Claims 17-21, 23, and 25 Rejected Under 35 U.S.C. § 103(a)

Claims 17-21, 23 and 25 were rejected in the present Office Action under 35 U.S.C. § 103(a) as being unpatentable over Aguadisch (EP 0 891 769) and Bar-Shalom *et al.* (US Pat No. 5,618,560). Aguadisch '769 was cited as disclosing pharmaceutical dosage forms produced by co-extrusion, in which a first component comprising silicone acts as a covering for a second composition, which contains a pharmaceutical agent. (Office Action, citing abstract and p. 5, lines 27-56 of Aguadisch '769). In the Office Action, it was also noted that the same reference is silent regarding a cooling step.

Bar-Shalom *et al.* '560 was cited as disclosing methods for creating extruded dosage forms with impervious outer layers and water-soluble inner cores, dosage forms which can be extruded. Bar-Shalom *et al.* '560 is further described in the Office Action as indicating that the dosage forms "are allowed to cool, before being cut." (Office Action, citing abstract).

Applicants respectfully submit that the Office Action has not established a *prima facie* case of obviousness of any of the present pending claims (after amendment as set forth above), under 35 U.S.C. §103(a), for the following reasons.

In order for any claim to be rejected, under 35 U.S.C. §103(a), a *prima facie* case of obviousness must be established. Section 2143.03 of the Manual of Patent Examining Procedure, 8th ed., rev. 2, Feb. 2003 (hereinafter, "MPEP") states that:

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

As was noted in the Office Action, Aguadisch '769 discloses a method of producing pharmaceutical dosage forms in which a first composition, a coating material, comprises a silicone composition. In the present method, the outer layer of the pharmaceutical dosage form is formed from components comprising a plasticizer and polymethacrylate or ethylcellulose. (language of claim 17, after

amendment). There is no requirement that any silicone derivative be used in the method of the present invention. Not only is there no such requirement in the language of the present claims. Silicone is not included as a component of any of the coating materials exemplified in the detailed description (see Table 1, page 10) or in the Examples. Aguadisch '769 neither teaches nor suggests that any coating material would be suitable for use in producing a dosage form by co-extrusion wherein the coating material does not include a silicone derivative.

Bar-Shalom *et al.* '560 discloses use of a coating layer, a "surface active agent," which is "substantially lipophilic." (Bar-Shalom *et al.* '560, col 1, lines 57-65). Examples of suitable surface active agents for use in that method included polyglycol esters or ethers, polyethylene glycol ester or ethers, polyhydroxy esters or ethers, and/or sugar esters or ethers. (see Bar-Shalom et al. '560, col. 5, lines 21-29). Claim 17 of the present application does not require the use of any such components in forming the outer layer of a dosage form according the method of the present invention.

Applicants respectfully submit that neither Aguadisch '769 nor Bar-Shalom *et al.* '560 alone, nor the two references viewed in combination with one another, disclose or suggest use of the coating layer composition in making co-extruded dosage forms according to the method of claim 17, after amendment. Specifically, Applicants submit that it would not have been obvious to one of ordinary skill in the art at the time the present invention was made that one could produce a controlled-release composition according to the method of the present invention without either a silicone derivative or a substantially lipophilic agent of the type disclosed in Bar-Shalom et al. '560.

For reasons set forth above, Applicants respectfully submit that the method of claim 17 is not obvious in view of the combination of Aguadisch '769 and Bar-Shalom *et al.* '560. Claims 18-21, 23, and 25 depend from claim 17, and are nonobvious for the same reasons given for claim 17. Therefore, Applicants respectfully request that the rejection of claims 17-21, 23, and 25, under 35 USC §103(a) be withdrawn.

C. New Claims Novel and Non-Obvious.

New claim 26 includes a statement that the diffusion-limiting sleeve element of the pharmaceutical dosage form of the invention comprise plasticizer and polymethacrylate or ethylcellulose. This component of the dosage form makes the dosage form novel and non-obvious in view of the individual or combined teachings of Aguadisch '769 and Bar-Shalom *et al.* '560, for the similar reasons to those given in the preceding section, above.

III. SUMMARY

Applicants respectfully submit that all the present pending claims (Claims 17-21, 23, and 25-28) are in condition for allowance, after amendment as set forth herein. Reconsideration and allowance of the claims is, therefore, respectfully requested. The Examiner is invited to contact the undersigned at the telephone number given below, should he wish to discuss the present amendment and suggest additional changes to the claims in order to further prosecution of the application.

Respectfully submitted,

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